IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

DALLAS R. LAVY and BEVERLY LAVY, his wife,

Plaintiffs, **Case No. _____**

Vs.

DEPUY, INC; DEPUY ORTHOPAEDICS, INC; JOHNSON & JOHNSON; and JOHNSON & JOHNSON SERVICES, INC., **JURY TRIAL DEMANDED**

Defendants.
_____/

COMPLAINT

Plaintiffs, DALLAS R. LAVY and BEVERLY LAVY, by their undersigned attorneys, sue the Defendants, DEPUY, INC., DEPUY ORTHOPAEDICS, INC., JOHNSON & JOHNSON, and JOHNSON & JOHNSON SERVICES, INC., and allege:

NATURE OF THE ACTION

1. This action arises from injuries sustained by the Plaintiff, DALLAS R. LAVY, as the result of being implanted with a defective metal-on-metal DePuy Pinnacle Acetabular Cup System (hereinafter "Pinnacle System" or "Pinnacle Device" or "Device" or "Product") into his right hip, which was designed, manufactured, marketed and sold by the Defendants.

2. Although the metal-on-metal Pinnacle System was not recalled, there have been numerous adverse event reports regarding failure and/or complications with resulting injury associated with the Device, and the Defendants ceased selling the metal on metal Pinnacle Hip system as of May 17, 2013.

3. More than 3,900 DePuy Pinnacle System cases have been filed in federal court,

and an MDL was created in this court, *In Re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation*, MDL No. 2244.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because Plaintiffs are residents of Montana and Defendant are residents of New Jersey and Indiana, creating complete diversity of citizenship, and the amount in controversy exceeds the sum of $75,000.00.

5. Venue is conditionally proper in the Northern District of Texas pursuant to Case Management Order No. 1 in *In re: Pinnacle Hip Implant Products Liability Litigation*, MDL No. 2244 which allows direct filing in that MDL case. But for the MDL case, Plaintiffs would have filed this claim in the District of Montana, Helena Division, because Defendants did business in that district and the action accrued in that district. Therefore, Plaintiffs request that, upon completion of discovery, their case be transferred back to the District of Montana for jury trial.

THE PARTIES

6. At all times material to this cause, Plaintiffs, DALLAS R. LAVY and BEVERLY LAVY, were residents of Townsend, Broadwater County, Montana, and were and are married and live together as husband and wife.

7. At all relevant times, Defendant, DEPUY, INC., was an Indiana corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. DePuy, Inc. is a subsidiary of Defendant, Johnson & Johnson.

8. At all relevant times, DEPUY, INC. was engaged in the business of designing, manufacturing, testing, labeling, marketing, distributing, selling, and introducing into interstate

commerce, either directly or indirectly, numerous orthopedic products, including the Pinnacle Hip System which is the subject of this lawsuit.

9. At all relevant times, DEPUY ORTHOPAEDICS, INC. (hereinafter "DePuy") was an Indiana corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Kosciusko County, IN 46581, and was a wholly owned subsidiary of Defendant, DePuy, Inc.

10. At all relevant times, Defendant, DePuy Orthopaedics, Inc. designed, manufactured, tested, labeled, marketed, distributed and sold the metal-on-metal Pinnacle Hip System, either directly or indirectly, to consumers throughout the United States, including the Pinnacle Hip which is the subject of this lawsuit.

11. At all relevant times, Defendant, JOHNSON & JOHNSON ("J&J"), was a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and was the parent company of DEPUY.

12. At all relevant times, Defendant J&J, as the parent company of DePuy, designed, manufactured, tested, labeled, marketed, distributed and sold the metal-on-metal Pinnacle Hip System, either directly or indirectly, to consumers throughout the United States, including the Pinnacle Hip which is the subject of this lawsuit.

13. At all relevant times, Defendant JOHNSON & JOHNSON SERVICES, INC. ("J&J Services"), was a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933 and participated in the designing, manufacturing, testing, marketing, distribution and sale of the metal-on-metal Pinnacle Hip System, including the Pinnacle Hip System which is the subject of this lawsuit.

GENERAL ALLEGATIONS

A. Nature and purpose of the Device

14. The Pinnacle Hip System was developed for the purpose of reconstructing diseased or fractured human hip joints. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits into a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

15. The metal-on-metal Pinnacle Device is made up of four components: the metal femoral stem is inserted inside the femur, and the metal femoral head (or ball) connects to the top of the stem and then makes contact with a liner which is inserted into the interior portion of the metal acetabulum cup (socket). The acetabular cup is comprised of titanium metal on its outer shell, and either a plastic, ceramic or metal liner is then placed on the inside of the acetabulum cup. The metal femoral head rotates within the plastic, ceramic or metal liner. A Pinnacle device whose components include a metal liner and a metal femoral head is a "metal-on-metal" system due to the fact that both articulating surfaces - the acetabular (socket) liner and femoral head (ball) - are comprised of cobalt-chromium metal.

B. Although Defendants' Hip System was a Class III Device, it was cleared for marketing as a Class II Device without premarket approval.

16. In 1976, the Medical Devices Amendment was passed, pursuant to which the FDA classified medical devices into three categories. A Class I category device poses almost no safety issues. A Class II category device poses moderate safety issues. A Class III device operates to sustain human life, is of substantial importance in preventing impairment of human health, or poses potentially unreasonable risks of harm to patients.

17. Generally, Class III devices must undergo the PreMarket Approval (PMA) process to be marketed in the United States. Premarket Approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, extensive clinical data to support the device's safety and effectiveness; a full statement of the device's components, ingredients, and properties, and of the principles of operation; a full description of the methods used in, and the facilities and controls used for, the design, manufacture, processing, and when relevant, packing and installation of, such device: samples or device components required by the FDA; and a specimen of the proposed labeling. When undergoing Premarket Approval, a Class III device may not use an existing device as a predicate, but rather the safety and effectiveness of the device must be independently shown.

18. The FDA may grant Premarket Approval only if it finds that there is reasonable assurance that the medical device is safe and effective, and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

19. The use of metal-on-metal hip joint replacement devices predates the Medical Device Amendments (MDA) of 1976. Metal-on-metal devices were formally classified into Class III on September 4, 1987. However, because these Class III devices predate the MDA, and because the criteria for Premarket Approval have not yet been established for these devices, metal-on-metal hip systems bypassed the rigorous scrutiny of the PreMarket Approval Process. Instead, they were and are "grandfathered in" and cleared for market through demonstrating substantial equivalence to other "predicate" metal-on-metal systems already on the market. This is the PreMarket Notification or 510(k) process by which a Class II or less risky device is cleared for market.

20. The metal-on-metal Pinnacle Device which is the subject of this lawsuit is a Class III medical device; however, it received clearance from the FDA through the 510(k) process generally reserved for Class II devices, which only requires a showing of substantial equivalence to a device already on the market. In obtaining clearance for marketing of the Pinnacle Device, DePuy bypassed the PreMarket Approval (PMA) process altogether.

C. Defendants knew or should have known that its metal-on-mental Hip System would lead to metallosis and other complications, but failed to test the Device prior to releasing it on the market.

21. DePuy Orthopaedics applied for clearance of its first metal-on-metal acetabular cup (with liner) on May 16, 2000 (K001523) based upon its substantial equivalence to four devices: ZTT II Acetabular Cup System (metal on plastic); Sulzer Orthopedics Inter-Op Metasul Acetabular System (metal/plastic liner on metal); and two first generation metal-on-metal hip systems, the McKee-Farrar and Ring. Clearance by the FDA for this device was received on August 18, 2000.

22. In fact, the McKee-Farrar Metal-on-Metal Hip and the Ring Metal-on-Metal hip date back to the 1960s but were eventually abandoned after tests found that patients had metal particles in their organs or blood, raising concerns about long-term health risks. In DePuy's product materials dated 2001, which promoted the metal liner (used with the Pinnacle acetabular shell), DePuy explained that clinical issues limited the success of the McKee-Farrar and Ring systems due to poor implant design, a limited understanding of design technology, and inadequate manufacturing processes.

23. On September 15, 2000, DePuy Orthopedics applied for clearance of the first Pinnacle Metal-on-Metal Acetabular Liner (K002883) based upon its substantial equivalence to

the DePuy Ultimet metal liner which had just been cleared on August 10, 2000 (K001523) – only 36 days earlier. The Pinnacle premarket notification contained neither any post-market Ultimet performance nor any clinical data, asserting only that the Pinnacle metal liner was the same as the Ultimet metal liner except for design changes that allowed the liner to be used with Pinnacle acetabular shells. Clearance by the FDA for this metal-on-metal liner was received on October 13, 2000. No subsequent metal Pinnacle liner notification has contained results from any clinical trials.

24. In 2001, DePuy published a brochure entitled "Ultamet Metal-on-Metal Articulation" which is designed to be used with the Pinnacle Acetabular Cup System. In that brochure, Depuy admitted that the McKee-Farrar, Muller, and Ring prostheses, *which were the very devices upon which it predicated its metal-on-metal Pinnacle system* ***were poorly designed and inadequately manufactured***:

> "Metal-on-metal articulation for total hip arthroplasty was originally introduced in the 1960s with implants such as the McKee-Farrar, Muller, Ring, Sivash and Stanmore prostheses. Metal-on-metal implants have survived in situ, often for more than 20 years, displaying minimal peri-implants osteolysis. The clinical issues limited the success of these first generation metal-on-metal implants resulted primarily from poor implant design, a limited understanding of design technology and inadequate manufacturing processes."

25. Nonetheless, DePuy marketed the metal-on-metal Pinnacle Device as having significant advantages over other first-generation hip devices, and touted the Product as having "superior clinical performance".

26. In 1996, Jonathan Black, Ph.D., an industry consultant and Clemson professor emeritus of bioengineering who specialized in production and biological sequelae of wear debris, warned in a medical journal article that metal-on-metal designs posed significant risks because

little was known about the biological havoc that metallic debris might cause. Dr. Black also argued that, given the high success rate of existing designs, it would be statistically impossible to run enough studies to prove the new implants' supposed superiority.

27. In its July 2005 issue, *The Journal of Bone and Joint Surgery* published the results of a study that retrospectively analyzed 165 patients (169 hips) who had undergone primary cementless total hip replacement with a contemporary metal-on-metal total hip design between 2000 and 2002. The findings of the study raised the fear that early osteolysis in patients with this second-generation metal-on-metal hip replacement is associated with abnormalities consistent with delayed-type hypersensitivity to metal.

28. Had Defendants heeded Dr. Black's warning and the warnings published thereafter, and closely monitored the performance of second generation metal-on-metal systems and the post-market experience of the metal-on-metal Pinnacle Device, they would have discovered that the Device results in a high percentage of patients developing metallosis, biologic toxicity and an early and high failure rate due to the release of metal particles in the patients' surrounding tissue when the cobalt-chromium metal femoral head rotates with the cobalt-chromium metal acetabular liner.

29. In other words, implantation of the metal-on-metal Pinnacle Device results in the nearly immediate systemic release of high levels of toxic metal cobalt-chromium ions into every hip implant patient's tissue and bloodstream. This is because cobalt-chromium metal particles are released by friction from the metal femoral head rotating within the metal liner. The particles then accumulate in the patient's tissue surrounding the implant giving rise to metallosis, pseudotumors, systemic toxic reactions, or other conditions.

30. The formation of metallosis, pseudotumors, and infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and lack of mobility. It further makes revision surgery exponentially more difficult to perform.

31. As of 2011, approximately 1,086 adverse event reports have been submitted to the U.S. Food and Drug Administration (FDA) regarding failures or complications of the metal-on-metal Pinnacle Devices.

32. At all relevant times, Defendants were aware that metal-on-metal Pinnacle Devices posed an unreasonably high risk of developing metallosis, biologic toxicity, and total hip failure, and Defendants were aware that the Devices resulted in unsafe release of toxic metal ions into the tissues and bloodstream of the hip implant recipients.

33. A number of governmental regulatory agencies have recognized the problems caused by metal-on-metal hip implants such as the Pinnacle Device. For instance, Great Britain's Medicines and Healthcare Products Regulatory Agency ("MHRA") investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. In April, 2010, MHRA issued a Medical Device Alert that required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate the for related soft tissue reactions.

34. Similarly, on May 28, 2010, the Alaska Department of Health issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

35. Despite the public knowledge to the contrary, Defendants continued to misrepresent the metal-on-metal Pinnacle System as a high-quality, safe and effective hip replacement product in their marketing and promotional materials. This is despite the fact that Defendants have known for years that the Pinnacle Device poses a danger to patients who have it implanted in them.

36. Until May 17, 2013, Defendants continued to sell the Pinnacle Device to health care facilities and doctors who implanted them in countless numbers of patients with an unreasonably high percentage of those patients being forced to endure serious injury from metallosis, pseudotumors, and biologic toxicity, among other complications. These patients are reporting severe pain and the need for one or more complicated revision surgeries, resulting in life-long health problems caused by the defective device.

D. Federal Requirements

37. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packaging, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. 351.

38. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. 352.

39. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by the FDA. These regulations require manufacturers to meet

design control requirements, including but not limited to, conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventative actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary and are required to use statistical techniques where necessary to evaluate product performance. *See* 21 CFR 820.

40. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR 820 et seq. as explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with, and implement, the basic requirements set forth in the quality system regulations.

41. Pursuant to 21 CFR 820.1(c), the failure to comply with any of these provisions in Part 820 renders a device adulterated under section 501(h) of the Federal Food, Drug & Cosmetic Act ("the Act")(21 U.S.C. 351).

42. Defendants' metal-on-metal Pinnacle Device is adulterated pursuant to 21 U.S.C. 351 because, among other things, it failed to meet established performance standards, in that it

caused severe injuries to recipients of the Device, including metallosis, pseudo-tumors, osteomyelitis and other conditions, which often required premature, painful revision surgery.

43. In addition, Defendants' metal-on-metal Pinnacle Device is misbranded because, among other things, it causes severe injuries to the recipients of the Device when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. 352.

E. Plaintiff's Pinnacle Implant and Injuries

44. On or about January 25, 2008, Plaintiff, DALLAS R. LAVY, underwent a right total hip replacement at Bozeman Deaconess Hospital in Bozeman, Montana by Daniel Gannon, MD. At that time, Plaintiff was implanted with a metal-on-metal 56mm Pinnacle Sector II cup, Ref. 1217-22-056, Lot CA3G81000; a Pinnacle metal insert, Ref. 1218-87-456, Lot 2463896; an Articul/eze M-Spec femoral head, Ref. 1365-05-000, Lot 2348046; and a DePuy Corail femoral stem, Ref. 3L92600, Lot 2431404.

45. Following surgery, Plaintiff's wounds healed without infection, and x-rays showed the hip replacement to be properly positioned and the hip replacement suffered no impacts.

46. On or about August 16, 2013, Mr. Lavy returned to Dr. Gannon with acute right hip pain. An MRI of his right hip showed no fluid collection. However, Dr. Gannon performed a right hip aspiration, which yielded 3cc mildly serosanguineous fluid. At that time, Dr. Gannon concluded that Mr. Lavy simply had bursitis.

47. In or about December, 2013, Mr. Lavy presented to Peter D. Hanson, MD, an orthopedist, for continuing intractable pain in his right hip. On January 14, 2014, Dr. Hanson aspirated the right hip at St. Peter's Hospital in Helena, Montana and retrieved 3.5ml of cloudy yellow fluid. A culture showed no growth.

48. On or about February 5, 2014, Mr. Lavy underwent a third right hip aspiration at St. Peter's Hospital by Jeffrey D. Georgia, MD, who aspirated 5ml of purulent fluid. Again, the culture was negative for infection. At that time, Dr. Hanson referred Mr. Lavy to Kerry S. Ford, MD for removal of the right hip and possible implant of an antibiotic spacer.

49. On or about March 5, 2014, Mr. Lavy underwent right hip revision surgery at St. Peter's Hospital in Helena, Montana by Kerry S. Ford, MD. Dr. Ford found that the acetabular cup and femoral stem were both well-placed, so exchanged only the acetabular liner and femoral head. At that time, Dr. Ford implanted a 40x56mm DePuy Pinnacle Altrx liner, Ref. 1221-40-156, Lot 429260, and a DePuy 40mm femoral head, Ref. 1365-40-710, Lot 3591265.

50. Subsequent to that surgery, Mr. Lavy's right hip symptoms vastly improved.

51. Plaintiff will require continuing metal ion testing and monitoring as a direct result of having been implanted with a defective metal on metal Pinnacle Hip implant.

52. As the direct result of the implantation of the metal on metal Pinnacle Hip System into Plaintiff, Plaintiff has suffered significant harm, including but not limited to, physical injury and disability, debilitating pain and lack of mobility, emotional distress, loss of quality of life, and has incurred substantial hospital, medical, nursing, rehabilitation, pharmaceutical, and other expenses, and said injuries are continuing.

53. All of the injuries suffered by the Plaintiff were caused by the defective design, warnings, construction and unreasonably dangerous character of the Pinnacle Device that was implanted into Plaintiff. Had Defendants not concealed the known defect, the early failure rate, the known complications and unreasonable risks of metallosis and failure associated with the use of the metal on metal Pinnacle Hip System, Plaintiff would not have consented to the metal on

metal Pinnacle Hip System being used in his total hip arthroplasty.

54. Plaintiff was unaware of any causal link between the injuries he suffered and any wrongdoing on the part of the Defendants due to the defective nature of the Pinnacle Hip due in part to the failure of Defendants to properly warn Plaintiff or his physicians, or issue any recall, or take other proactive action regarding the Pinnacle Hip's defective and faulty nature from prior to the time he was implanted with the hip to the time his hip was revised on March 5, 2014.

COUNT I
(Strict Liability - Defect in Design)

55. Plaintiffs incorporate and reallege the General Allegations in paragraphs 1 through 54 in Count I of this Complaint.

56. At all times material hereto, Defendants engaged in the business of designing, developing, manufacturing, testing, packaging, labeling, distributing, marketing, selling, and/or distributing, the DePuy Pinnacle Hip System.

57. The Pinnacle System was intended for use in hip replacement procedures for consumers, and Plaintiff, DALLAS R. LAVY, was a consumer and relied upon the manufacturing safety of the device.

58. At all relevant times, Defendants expected the Pinnacle System to reach, and it did reach, consumers in the State of Montana, including Plaintiff, without substantial change in the condition in which it was sold.

59. The Pinnacle System was defectively designed, manufactured, and/or tested so as to be unreasonably dangerous to consumers and to Plaintiff at the time it was placed into the stream of commerce, in that:

a) When placed in the stream of commerce, the device contained unreasonably dangerous design and manufacturing defects and was not reasonably safe as intended to be used, subjecting the Plaintiff to an unreasonably high risk of failure of the total hip replacement and the necessity of further invasive surgery;

b) When placed in the stream of commerce, the device created unreasonably high risk of failure which exceeded the benefits of the device;

c) When placed in the stream of commerce, the device was more dangerous than an ordinary consumer would expect and more dangerous than other similar prosthetic hip components that were already on the market;

d) When placed in the stream of commerce, the device failed to comply with federal requirements.

60. The Pinnacle System that was implanted into the Plaintiff had not been materially altered or modified prior to the implantation of the devices.

61. Plaintiff was a foreseeable user of the device and the device was implanted into him for its intended purpose, a total hip replacement.

62. Had the Pinnacle System not been defective, Plaintiff would not have sustained the injuries alleged herein.

63. As the direct and proximate result of the defective design of the Pinnacle System, the Plaintiff, DALLAS R. LAVY, was implanted with a Pinnacle System on January 25, 2008, and suffered painful failure of that hip replacement, which necessitated additional revision hip surgery.

64. As a further proximate result of the defective design of the Pinnacle System, Plaintiff suffered debilitating physical and mental pain; was required to undergo additional hip surgery; incurred substantial hospital, medical, nursing and rehabilitative expenses therefrom; suffered emotional distress; disability; and lost quality of life, and all of these injuries are permanent and continuing.

WHEREFORE, Plaintiff, DALLAS R. LAVY, demands judgment against Defendants, DEPUY, INC., DEPUY ORTHOPAEDICS, INC., JOHNSON & JOHNSON, and JOHNSON & JOHNSON SERVICES, INC., for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT II
(Strict Liability – Manufacturing Defect)

65. Plaintiffs reallege and incorporate the General Allegations contained in Paragraphs 1 through 54 in Count II of this Complaint.

66. At all relevant times, Defendants manufactured, designed, distributed, and/or sold the DePuy Pinnacle Hip System that was implanted into the Plaintiff, DALLAS R. LAVY

67. The Pinnacle System was intended for use in hip replacement procedures for consumers, and Plaintiff was a consumer who relied upon the manufacturing safety of the device.

68. At all relevant times, Defendants expected the Pinnacle System to reach, and it did reach, consumers in the State of Montana, including Plaintiff, without substantial change in the condition in which it was sold.

69. The Pinnacle System that was manufactured, designed, marketed, distributed, sold and/or placed in the stream of commerce by the Defendants was defective in its manufacture and construction in that, when it left the hands of the Defendants, it deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury to the consumer into whom it was implanted.

70. Plaintiff was a foreseeable user of the device and the device was implanted into him for its intended purpose, i.e. a total hip replacement.

71. Had the Pinnacle System not been defectively manufactured, Plaintiff would not

have sustained the injuries alleged herein.

72. As the direct and proximate result of the defects in the Pinnacle System, Plaintiff, DALLAS R. LAVY, was implanted with the aforementioned Pinnacle hip on January 25, 2008 and suffered painful failure of his right hip replacement, which necessitated additional revision hip surgery.

73. As a further proximate result of the defective manufacturing of the Pinnacle System, Plaintiff suffered debilitating physical pain and mental pain; was required to undergo additional hip surgery; incurred substantial hospital, medical, nursing and rehabilitative expenses therefrom; suffered emotional distress; disability; and lost quality of life, and all of these injuries are permanent and continuing.

WHEREFORE, Plaintiff, DALLAS R. LAVY, demands judgment against Defendants, DEPUY, INC., DEPUY ORTHOPAEDICS, INC., JOHNSON & JOHNSON, and JOHNSON & JOHNSON SERVICES, INC., for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT III
(Strict Liability - Failure to Warn)

74. Plaintiffs reallege and incorporate the General Allegations contained in Paragraphs 1 through 54 in Count III of this Complaint.

75. At all relevant times, Defendants manufactured, designed, tested, distributed and/or sold the DePuy Pinnacle Hip System that was implanted into the Plaintiff, DALLAS R. LAVY

76. The Pinnacle System that was implanted into the Plaintiff was defective and unreasonably dangerous when it left the possession of the Defendants in that:

a) The device contained insufficient warnings to alert consumers and their prescribing physicians that the Pinnacle System posed an unreasonably high risk of failure once implanted;

b) Defendants' promotional materials, labeling and instructional materials that accompanied the Pinnacle System were inadequate and misleading to consumers and their prescribing physicians;

c) Even after Defendants received notice from reputable medical sources prior to the sale of the device to the Plaintiff, that the devices presented an inordinately high risk of failure and harm to the consumer, Defendants knowingly and deliberately failed to warn the public, including Plaintiff and his prescribing physician, of the serious risk of injury and failure occasioned by the defects in the device;

d) The Pinnacle System did not conform to the representations made by Defendants concerning the devices;

e) Defendants' representations concerning the Pinnacle System did not conform to applicable federal requirements;

77. The Defendants, as manufacturers of the Pinnacle System, are held to the level of knowledge of experts in the field of that type of prosthetic device, and had a duty to warn their consumers and prescribing physicians of the dangers associated with the device and failed to do so.

78. At the time Plaintiff's physician prescribed and implanted the device, the physician did not have substantially the same knowledge as the Defendants about the unreasonably high risks of failure of the Pinnacle System because Defendants failed to provide adequate warnings of those risks to him.

79. As the direct and proximate result of Defendants' failure to warn of the defective condition of the Pinnacle System, the Plaintiff, DALLAS R. LAVY, was implanted with the Pinnacle System on January 25, 2008 and suffered painful failure of his hip replacement, which necessitated painful revision surgery.

80. As a further proximate result of Defendants' failure to warn of the defective condition of the Pinnacle System, Plaintiff suffered debilitating physical and mental pain; was required to undergo additional hip surgery; incurred substantial hospital, medical, nursing and rehabilitative expenses therefrom; suffered emotional distress; disability; and lost quality of life, and all of these injuries are permanent and continuing.

WHEREFORE, Plaintiff, DALLAS R. LAVY, demands judgment against Defendants, DEPUY, INC., DEPUY ORTHOPAEDICS, INC., JOHNSON & JOHNSON, and JOHNSON & JOHNSON SERVICES, INC., for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT IV
(Negligence)

81. Plaintiffs incorporate and reallege Paragraphs 1 through 54 into Count IV of this Complaint.

82. At all times material hereto, Defendants, directly or indirectly, created, manufactured, assembled, designed, sterilized, tested, packaged, labeled, marketed, promoted, advertised, sold and/or distributed the DePuy Pinnacle Hip System, including the Pinnacle Hip that was implanted into the Plaintiff, DALLAS R. LAVY.

83. At all relevant times, Defendants owed a duty to the public and to the Plaintiff to exercise reasonable care in the design, manufacture, testing, processing, advertising, marketing, testing, labeling, assembling, packaging, distribution, promotion and sale of the Pinnacle Device.

84. Defendants negligently breached that duty to the Plaintiff in that:

a) Defendants designed, manufactured and sold the device that they knew or should have known created an unreasonably high risk of failure when implanted into patients, including the Plaintiff;

b) Defendants failed and/or refused to include adequate warnings with the device that would alert Plaintiff and his prescribing physician to the potential risks and serious side effects of the device;

c) Defendants failed and/or refused to adequately and properly test the device before placing the device on the market;

d) Defendants failed to conduct sufficient testing on the device both before and after the device was placed on the market which, if properly performed, would have shown that the device caused serious side effects, including, but not limited to, severe pain and disability, metallosis, synovitis, and failure of the total hip replacement;

e) Defendants failed to adequately warn the Plaintiff or his prescribing physician that the device caused or was associated with an unreasonably high risk of failure and pain, debilitating side effects;

f) Defendants failed to warn, or adequately warn the Plaintiff or his prescribing physician that the device created a higher risk of failure than other similar devices currently on the market;

g) Defendants failed to provide adequate post marketing warnings or instructions to the Plaintiff and/or his prescribing physician of the significant risk of injury and failure of the total hip replacement associated with the device;

h) Defendants placed an unsafe and defective hip prosthetic device into the stream of commerce;

i) Defendants failed to conform to the applicable federal laws and regulations in designing, manufacturing, marketing, selling and distributing the device;

j) Defendants underplayed the significant risk of failure of the device to the public, including the Plaintiff and/or his prescribing physician in order to make a profit from sale of the device.

85. Defendants knew or should have known that Pinnacle System caused unreasonably dangerous risks and serious side effects of which the Plaintiff and his prescribing physician would not be aware, but nevertheless advertised, marketed, sold and distributed the device knowing that there were safer comparable products for hip replacements.

86. As a direct and proximate result of Defendant's negligent acts and omissions, Plaintiff, DALLAS R. LAVY, was implanted with the Pinnacle System on January 25, 2008, and suffered painful failure of his hip replacement, which necessitated revision surgery.

87. As a further proximate result of Defendants' negligent acts and omissions, Plaintiff suffered debilitating physical pain and mental distress; was required to undergo additional hip surgery; incurred substantial hospital, medical, nursing and rehabilitative expenses therefrom; suffered emotional distress; disability; and lost quality of life, and all of these injuries are permanent and continuing.

WHEREFORE, Plaintiff, DALLAS R. LAVY, demands judgment against Defendants, DEPUY, INC., DEPUY ORTHOPAEDICS, INC., JOHNSON & JOHNSON, and JOHNSON & JOHNSON SERVICES, INC., for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT V
(Negligent Misrepresentation)

88. Plaintiffs incorporate and reallege Paragraphs 1 through 54 into Count V of this Complaint.

89. At all relevant times, Defendants knew or should have known that their Pinnacle Hip System that was implanted into Plaintiff, DALLAS R. LAVY, was defective, and failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification. Yet Defendants negligently misrepresented to the Plaintiff and/or his physicians that the device was safe and met all applicable design and manufacturing requirements.

90. The Plaintiff and/or his physicians reasonably relied upon Defendants' misrepresentations and omissions concerning the safety of the device to Plaintiff's detriment.

91. As the direct result of Defendants' negligent misrepresentations and omissions and/or failure to disclose its violations of federal requirements applicable to its Pinnacle System, Plaintiff was implanted with a Pinnacle Hip System and suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff, DALLAS R. LAVY, demands judgment against Defendants, DEPUY, INC., DEPUY ORTHOPAEDICS, INC., JOHNSON & JOHNSON, and JOHNSON & JOHNSON SERVICES, INC., for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT VI
(Fraudulent Misrepresentation)

92. Plaintiffs incorporate and reallege Paragraphs 1 through 54 into Count VI of this Complaint.

93. On or about January 25, 2008, Plaintiff, DALLAS R. LAVY, was implanted with DePuy Pinnacle Hip System in his right hip, which was designed, manufactured, packaged, labeled, marketed, distributed and/or sold by the Defendants.

94. At the time Plaintiff purchased and was implanted with the Pinnacle Device, Defendants had actual knowledge that the device was defective in that it created an unreasonably high risk of injury to the tissues surrounding the implant and created an unreasonably high risk of failure of the implant when implanted and used as directed.

95. Despite Defendants' actual knowledge of the unreasonably high risk of failure of the device and/or severe injury to the recipient of the device, and despite complaints and adverse event reports that Defendant received concerning defects in the Pinnacle System, Defendants

acted with gross negligence and willful and wanton disregard of the safety of the general public and of the Plaintiff in knowingly and intentionally continuing to market, promote and sell the device with no warning concerning the known high risk of failure and injury, so as to maximize their sales and profits at the expense of the health and safety of the public and of the Plaintiff.

96. Defendants' culpable fraudulent misrepresentations to the public and to Plaintiff include, but are not limited to:

a) Failing or refusing to conduct adequate pre-market and post-market testing of the device;

b) Failing or refusing to conduct adequate testing of the device even after having received numerous adverse event reports and complaints that the Pinnacle Systems had a high risk of failure and a high risk of causing severe side effects when implanted and used as directed;

c) Failing or refusing to warn consumers and their prescribing physicians, including the Plaintiff, that the device had a high risk of failure and of causing serious injury;

d) Intentionally omitting any mention on the advertisements and labeling that the use of the device had been associated with an unreasonably high risk of component loosening, component malalignment, infection, metallosis, bone fracture, dislocation and pain, despite the fact that Defendants were made aware of adverse event reports and complaints long before the Plaintiff was implanted with the device;

e) Intentionally failing and refusing to change the label of the device to reflect the high risk of failure of the devices and injury to its recipient;

f) Engaging in a promotional campaign for the Pinnacle Devices that minimized the high risk of serious injuries and the need for revision surgery caused by the device, and embarking on a campaign that discounted reports of failure of the device and injury to the recipients of the device;

g) Falsely and fraudulently representing to the medical community and to the Plaintiff and/or the FDA, and the public in general, that the devices had been tested and were found to be safe and/or effective as a hip replacement system.

97. All of the above misrepresentations and concealments of the Defendants were

intentional acts specifically directed to keep safety concerns about the Pinnacle Device from decrease in the sales of the Device, and were undertaken with the intent that Plaintiff and other consumers would rely upon them.

98. Defendants' misrepresentations and concealments were undertaken with the intent of defrauding and deceiving Plaintiff and other consumers, to induce and encourage the sale of the Pinnacle System.

99. If the representations and warnings concerning the Pinnacle Device had been accurate and truthful, such representations and warnings would have dissuaded the Plaintiff and his prescribing physicians from purchasing or using the device and Plaintiff would not have used the Pinnacle System had he known it would cause him to suffer subsequent pain and disability, and require a total hip revision surgery six years later.

100. Plaintiff relied upon and was induced by Defendants' misrepresentations, omissions and/or active concealment of the dangers of injury and further surgery in selecting the Pinnacle Device to his detriment.

101. The aforementioned actions of Defendants constituted knowing and intentional misconduct and/or conduct undertaken with reckless, willful and wanton disregard for the safety of the public and of the Plaintiff, and such conduct was at all times ratified by the Defendants.

102. As the direct and proximate result of Defendants' fraudulent misrepresentations and omissions, Plaintiff, DALLAS R. LAVY, was implanted with a Pinnacle Hip System on January 25, 2008 and suffered painful failure of his hip replacement, which caused him severe pain and disability and necessitated revision surgery.

103. As the further proximate result of Defendants' fraudulent misrepresentations,

Plaintiff suffered debilitating physical pain and mental suffering; was required to undergo additional hip surgery; incurred substantial hospital, medical, nursing and rehabilitative expenses therefrom; suffered emotional distress; disability; and lost quality of life, and all of these injuries are permanent and continuing.

WHEREFORE, Plaintiff, DALLAS R. LAVY, demands judgment against Defendants, DEPUY, INC., DEPUY ORTHOPAEDICS, INC., JOHNSON & JOHNSON, and JOHNSON & JOHNSON SERVICES, INC., for compensatory and punitive damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT VII
(Consortium Claim)

104. Plaintiffs incorporate and reallege all preceding paragraphs into Count VII of this Complaint.

105. At all relevant times, Plaintiff, BEVERLY LAVY, was the wife of DALLAS R. LAVY, and, as the result of the injuries sustained by her husband as hereinabove alleged, has lost the services, support, companionship, affection and consortium of her husband, and will continue to lose said services, companionship, affection and consortium in the future, and has in the past and will in the future become obligated to pay medical expenses on behalf of her husband.

WHEREFORE, Plaintiff, BEVERLY LAVY, demands judgment against Defendants, DEPUY, INC., DEPUY ORTHOPAEDICS, INC., JOHNSON & JOHNSON, and JOHNSON & JOHNSON SERVICES, INC., for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

Dated August 6, 2014.

_/s/ Joseph H. Saunders_____
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